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MAIL STOP PCT
Attorney Docket: 26964U

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
SCHMIDT

Art Unit: Unknown
Examiner: Unknown

Filed: September 20, 2005

Application No.: 10/549,631

Title: **PROCESS FOR PREPARING CRYSTALLINE CICLESONIDE WITH
DEFINED PARTICLE SIZE**

TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

- 1) Information Disclosure Statement;
- 2) PTO Form-1449 with 31 cited references;
- 3) Copies of 22 of the 31 cited references.

The Commissioner is hereby authorized to charge any deficiency or credit any excess to Deposit Account No. 14-0112.

Date: December 7, 2005

Respectfully submitted,
NATH & ASSOCIATES PLLC

By: _____

Gary M. Nath
Reg. No. 26,965
Sheldon M. McGee
Reg. No. 50,454
Customer No. 34375

NATH & ASSOCIATES PLLC
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Washington, D.C. 20005-1503
GMN/SMM/LE (IDS)



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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

An Information Disclosure Statement is submitted herewith pursuant to 37 C.F.R. 1.97-1.98. Please note the following particulars: [NOTE: One only of items a, b, c, and d must be checked.]

[XXX] a. The enclosed statement is being filed within three months of the filing date of a national application, or within three months of the date of entry into the national stage as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing date of a first Office Action on the merits, whichever event occurs last.

[] b. The enclosed statement is being filed after a first action on the merits but before the mailing date of a final action under 37 C.F.R. 1.113, or a notice of allowance under 37 C.F.R. 1.311.

The enclosed statement is accompanied by [check one]:

[] i. a certification in part (e) below as specified in 37 C.F.R. 1.97(e), or

[] ii. a check in the amount required by 37 C.F.R. 1.17(p).

[] c. The enclosed statement is being filed after the mailing date of a final action under 37 C.F.R. 1.113, or a notice of allowance under 37 C.F.R. 1.311, but before payment of the issue fee.

[] Certification report(e) below; and

[] a check in the amount as required by 1.17(p).

[] d. The enclosed statement is being filed pursuant to 37 C.F.R. 1.97(i), for placement in the file.

[] e. Certification [Check one] [Certification is required only if box (b)(i) or box (c) is checked.]

[] I hereby certify that each item of information contained in the enclosed Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement,

or

[] I hereby certify that no item of information in the enclosed Information Disclosure Statement herewith was cited in a communication from a foreign patent office in a counterpart foreign application, or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

or

[] Appropriate certification is attached.

[XXX] f. If no check is enclosed and a fee is due in connection with this communication or if the check enclosed is insufficient, the Commissioner is authorized to charge any fee or additional fee due in connection with this communication to Deposit Account No. 14-0112.

[XXX] g. Copies of the documents are attached herewith with a completed Form PTO-1449.

or

[] Copies of the documents are not attached as allowed under CFR 1.98(d)(1)(2). The earlier application is identified as:

and / or

[XXX] Copies of US Patents/Publications not attached as allowed in Official Gazette Aug. 5, 2003/ Vol. 1273, no. 1.

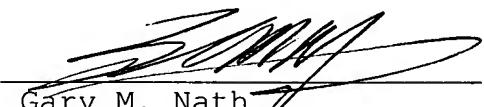
The Examiner is respectfully requested to cite the documents listed on the attached Form PTO-1449 in the next Office Action. In so doing, the Examiner is respectfully requested to initial in the space adjacent to the listing of each document on the Form PTO-1449, and return a copy of the initialed Form PTO-1449 with the next communication to Applicants, to confirm that these documents have been considered by the Examiner and made of record in this application.

If the Examiner has any questions or wishes to discuss this application, kindly telephone the undersigned at the below-listed number.

Date: December 7, 2005

Respectfully submitted,
NATH & ASSOCIATES PLLC

By: _____


Gary M. Nath
Reg. No. 26,965
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DEC 07 2005

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FORM PTO-12448

INFORMATION DISCLOSURE CITATION

In re Application of:

SCHMIDT

Art Unit:

Unknown

Application No:

10/549,631

Filed:

September 20, 2005

Examiner:

Unknown

U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Issue / Publication Date	Inventor	Filed
	A1	2005/0080063 A1	04/14/2005	Schmidt	11/06/2001
	A2	5,728,826	03/17/1998	Gutterer	03/07/1995
	A3	5,733,901	03/31/1998	Gutterer	03/31/1994
	A4	5,482,934	01/09/1996	Calatayud et al.	07/20/1994
	A5	6,787,533 B1	09/07/2004	Gutterer	08/29/1997

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		Document Number	Publication Date	Country	Translation
	A6	0 142 309 A2	05/22/1985	EP	N/A
	A7	41 29 535 A1 (Corresponds to English US5482934)	03/12/1992	DE	Abstract
	A8	195 41 689 A1	05/15/1996	DE	Abstract
	A9	196 35 498 A1	03/26/1998	DE	Abstract
	B1	0 142 309 B1	05/22/1985	EP	N/A
	B2	0 407 028 B1	01/09/1991	EP	N/A
	B3	0 505 321 A2	09/23/1992	EP	Abstract
	B4	0 650 410 B1	05/03/1995	EP	N/A

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	B5	Ruch, F, Matijevic, E., "Preparation of Micrometer Size Budesonide Particles by Precipitation", <u>Journal of Colloid and Interface Science</u> , vol. 229, pp. 207-211 (2000)
	B6	Hem, S.L. et al., "Mechanism of Crystallization of Hydrocortisone by Ultrasonic Irradiation", <u>J. of Pharm. Sciences</u> , vol. 56, no. 2, pp. 229-233 (1967)
	B7	Sjostrom, B. et al., "A Method for the Preparation of Submicron Particles of Sparingly Water-Soluble Drugs by Precipitation in Oil-in-Water Emulsions. II: Influence of the Emulsifier, the Solvent, and the Drug Substance", <u>J. of Pharm. Sciences</u> , vol. 82, no. 6, pp. 584-589 (1993)

Examiner

Date Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP ' 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

DEC 07 2005

Attorney Docket: 26964U

FORM PTO-1449

INFORMATION DISCLOSURE CITATION

In re Application of:

SCHMIDT

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Examiner:

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U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Issue / Publication Date	Inventor	Filed
	B8	4,605,517	08/12/1986	Riley et al.	10/11/1984
	B9	6,264,923 B1	07/24/2001	Oliver et al.	11/15/1999
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	C2	6,120,752	09/19/2000	Oliver et al.	05/13/1998

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	C4	0 725 725 B1	08/14/1996	EP	N/A
	C5	99/21601 A1	05/06/1999	WIPO	N/A
	C6	98/09982 A1	03/12/1998	WIPO	N/A
	C7	92/08730 A1	05/29/1992	WIPO	Abstract
	C8	90/03782 A2	04/19/1990	WIPO	N/A
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	D2	01/28562 A1	04/26/2001	WIPO	N/A
	D3	01/00046 A1	01/04/2001	WIPO	Abstract
	D4	00/38811 A1	07/06/2000	WIPO	N/A

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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